

REMARKS

This is intended as a full and complete response to the Office Action dated October 18, 2005, having a shortened statutory period for response extended one month and set to expire on February 20, 2006. Please reconsider the claims pending in the application for reasons discussed below.

Claim Rejections – 35 U.S.C. § 112

Claims 11-19 stand rejected under 35 U.S.C. § 112, second paragraph. Applicants respectfully traverse the rejection.

Applicants have amended claim 11 to clarify that the product of the claimed method is the fibroblasts and the differentiation is the substantially homogenous population which occurs due to the embryoid bodies being embedded in the gel. In claim 16, "the differentiated cells" phrase has been amended to state "the fibroblasts," which has antecedent basis. Applicants have additionally amended claims 15 and 18 to remove the phrases cited by the Examiner as being unclear. Accordingly, Applicants submit that claims 11-19 are in compliance with 35 U.S.C. § 112, second paragraph, and request withdrawal of the rejection and allowance of the claims.

Claim Rejections – 35 U.S.C. § 102

Claims 11-13 and 16-18 stand rejected under 35 U.S.C. § 102(b), as being anticipated by *Dani et al.* ("Differentiation of Embryonic Stem Cells into Adipocytes In Vitro," Journal of Cell Science (1997); 110: 1279-1285). Applicants respectfully traverse the rejection.

Claim 11 recites the limitations of "casting the embryoid bodies in a three-dimensional scaffolding material and a cell culture medium, wherein the three-dimensional scaffolding material is a gel; and growing the embryoid bodies embedded in the three-dimensional scaffolding material." However, *Dani et al.* fails to disclose embryoid bodies embedded in a gel. In contrast, embryoid bodies of a differentiation

method taught in *Dani et al.* are maintained as hanging drops in cultivation medium followed by suspension in the cultivation medium and subsequent settling onto gelatin-coated plates. Therefore, there is no teaching in *Dani et al.* that the cultivation medium provides a gel or that the embryoid bodies are otherwise embedded in a gel at any time.

Dani et al. fails to teach, show or suggest each and every element of claim 11. Applicants submit that claim 11 and all claims dependent thereon are allowable. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of claims 11-13 and 16-18.

Claim Rejections – 35 U.S.C. § 103

Claims 11-13 and 15-18 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over *Dani et al.* in view of *Gold et al.* (U.S. Patent No. 6,576,464). Applicants respectfully traverse the rejection.

As stated above regarding the § 102 rejection, *Dani et al.* does not teach, show or suggest “casting the embryoid bodies in a three-dimensional scaffolding material and a cell culture medium, wherein the three-dimensional scaffolding material is a gel; and growing the embryoid bodies embedded in the three-dimensional scaffolding material,” as recited in claim 11. Further, *Gold et al.* fails to overcome this deficiency in *Dani et al.* Therefore, *Dani et al.* in view of *Gold et al.* cannot render claim 11 obvious. Applicants submit that claim 11 and claims 12-13 and 15-18 dependent thereon are allowable and request withdrawal of the rejection and allowance of these claims.

Claim Rejections – 35 U.S.C. § 112

Claims 11-19 stand rejected under 35 U.S.C. § 112, first paragraph. In response, Applicants respectfully traverse the rejection.

Regarding subsection 1 identified in the Office Action, the specification of the present application at the last two sentences of paragraph [0058] clarify the Examiner's misinterpretation of paragraphs [0056] and [0057] of the disclosure by stating that differentiation does occur with TGF-beta and IL-4 but over a longer period of time. As

for the state of the prior art, the prior art does not utilize the method of the claimed invention which enables differentiation based on the embedding of embryoid bodies in a gel. Therefore, it is inappropriate to compare the substances utilized in the claimed invention with the prior art. Further, examples have been provided in the specification that used TGF-beta and IL-4 proving that the invention is enabled.

Applicants further traverse the rejection as applied in subsection 2 of the Office Action. While there are differences in primate and mouse development as stated in *Thompson* (U.S. Patent No. 5,843,780), these differences cited (timing of expression, formation of an egg cylinder, etc.) do not demonstrate that any undue experimentation would be required with regard to the invention as claimed. Further, *Mandalam, et al.* (U.S. Publication No. 2003/0017589) is yet another example of prior art that does not utilize the method of the claimed invention which enables differentiation based on the embedding of embryoid bodies in a gel. Additionally, examples have been provided in the specification that used FGF, thereby proving that the invention is enabled.

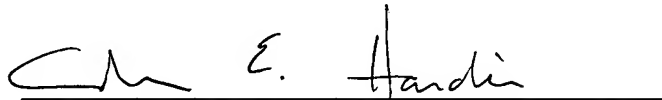
With respect to subsection 3 of the Office Action, *Schuldiner, et al.* ("Effects of Eight Growth Factors on the Differentiation of Cells Derived from Human Embryonic Stem Cells," PNAS October 2000; Vol. 97, No. 21, pages 11307-11312) is once again an example of prior art that does not utilize the method of the claimed invention which enables differentiation based on the embedding of embryoid bodies in a gel. As stated in the present specification at, for example, paragraph [0006], embryoid bodies differentiate reproducibly and stably into fibroblasts in the presence or absence of cytokines when the methods for culturing embryoid bodies in the gel are utilized. Accordingly, the recited cytokines in the claims can enhance differentiation as contemplated in some embodiments but are not the source for directing exclusive differentiation.

Based on the foregoing, Applicants submit that claims 11-19 are in compliance with 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

Conclusion

The references cited by the Examiner, alone or in combination, do not teach, show, or suggest the invention as claimed. Having addressed all issues set out in the office action, Applicants respectfully submit that the claims are in condition for allowance and respectfully request that the claims be allowed.

Respectfully submitted,

A handwritten signature in cursive script, reading "Chance E. Hardie", is written over a horizontal line.

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